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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,058	11/10/2000	David Anderson	A-68531-1/RMS/JJD/SPL	4112

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EXAMINER
CELSA, BENNETT M

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/710,058	Anderson et al.
Examiner	**Art Unit**
Bennett Celsa	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-9* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 1-9 are currently pending and under consideration.

Election/Restriction

1. Applicant's election without traverse of Group I (claims 1-9) and the species rGFP in Seq. Id. 1 in Paper No. 10 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (lack of written description).

The present claims are directed to one or more (e.g. library) of cells or vectors comprising pGFP or rGFP (e.g. nucleotides that encode green fluorescent proteins) alone or in a fusion construct

The specification description is directed to specific nucleotide sequences (e.g. seq. 1) that encode green fluorescent proteins of specific peptide sequence (e.g. amino acid content and length)

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

In the present instance, the claimed invention contains no identifying characteristics regarding the DNA chemical structure which encodes a renilla green fluorescent protein e.g. the claims do not set forth any common features possessed by members of the genus of nucleotides encoding renilla green fluorescent proteins that distinguished them from other nucleotide encoding sequences. Additionally, the narrow scope of examples directed to specific nucleotide sequences which encode specific green fluorescent proteins are clearly not representative of the scope of renilla nucleotide encoding sequences of the presently claimed invention..

In this regard, applicant is referred to the seminal case of *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and the resulting "Guidelines for Examination of Patent Applications Under the 35 USC 112, first paragraph, 'Written Description' Requirement" published in 1242 OG 168-178 (January 30, 2001).

It is first noted that written description is legally distinct from enablement: "Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co*

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

As pointed out in the above rejection, the specification discloses only limited examples that are neither representative of the claimed genus of reactions, nor is it clear that they represent a substantial portion of the claimed genus.

When the fed. circuit addressed a similar issue in Eli Lilly, it was determined that a disclosure of the sequence of rat cDNA was not descriptive of the broader invention consisting of

mammalian and vertebrate cDNA, although it was a species falling within the scope of those claims. Eli Lilly, 119 F.3d at 1567-68, 43 USPQ2d at 1405. In Eli Lilly, the specification and generic claims to all cDNAs encoding for vertebrate or mammalian insulin did not describe the claimed genus because they did not set forth any common features possessed by members of the genus that distinguished them from others. Id. At 1568, 43USPQ2d at 1405. Nor did the specification describe a sufficient number of species within the very broad genus to indicate that the inventors had made a generic invention, i.e., that they had possession of the breadth of the genus, as opposed to merely one or two such species. E.g. See *Enzo Biochem. Inc.v. Gen-Probe Inc.*, Case No. 01-1230 (Fed. Cir. July 15, 2002) ("EnzoII").

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35

U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

6. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Aran et al. Cancer Gene Ther. (July/Aug 1998) pages 195-206.

Aran et al. (e.g. see abstract and entire article) disclose retroviral vectors which "comprise" a GFP gene (e.g. a red-shifted green fluorescent protein) and which further include a "first gene" (e.g. for multridrug resistance: MDR) and an internal ribosome entry site (e.g. IRIS)

which is expressed in living cells (e.g. "A cell" as presently claimed); along with Beta galactosidase. The reference GFP gene is within the scope of the presently claimed invention (e.g. "a p- or rGFP gene") since it encodes a GFP protein and it meets the presently claimed structural requirement (e.g its a gene) since the presently claimed invention is not limited to any specific genetic sequence.

7. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Abedi et al. Nuc. Acid Res. Vol. 26, No. 2 (1998).

Abedi et al (e.g. see abstract and entire article). teach the making of genetic constructs expressed within cells (e.g. E. Coli/yeast) of fusion proteins comprising "random peptide" and green fluorescent protein. The constructs additionally comprise a "fusion partner" which corresponds to nucleotide linking sequence or peptide sequence leading to the formation of a conformational constraint. In this regard, the presently claimed invention fails to define the term "fusion partner" structurally or functionally; nor does the specification provide a specific closed definition of this terminology. Additionally, the reference GFP gene is within the scope of the presently claimed invention (e.g. "a p- or rGFP gene") since it encodes a GFP protein and it meets the presently claimed structural requirement (e.g its a gene); since the presently claimed invention is not limited to any specific genetic sequence.

8. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. US Pat. No. 6,180,343 (1/01: filed 10/98). .

Anderson et al teach the use of green fluorescent proteins (e.g. see col. 2-3) in "random" and "defined" peptides fusion constructs (E.g. see col. 1, especially lines 1-15; col. 7-8) in retroviral vectors (e.g. libraries: see col. 19-20) which are expressed in cells to form libraries (e.g. cells; for screening). The genetic constructs further comprise internal ribosome entry sites (IRES: see col. 17, lines 15-30; col. 27, especially lines 5-20) and "fusion partners" (e.g. see col. 7-12 et seq.) within the scope of the presently claimed invention. Additionally, the reference GFP gene is within the scope of the presently claimed invention (e.g. "a p- or rGFP gene") since it encodes a GFP protein and it meets the presently claimed structural requirement (e.g its a gene); since the presently claimed invention is not limited to any specific genetic sequence.

Claim Rejections - 35 USC § 103

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. US Pat. No. 6,180,343 (1/01: filed 10/98) and Bryan et al. US Pat. No. 6,232,107 (5/01: filed 10/98 or earlier)with attached Result 4 DATABASE Alignment search..

Anderson et al teach the use of green fluorescent proteins (e.g. see col. 2-3) in "random" and "defined" peptides fusion constructs (E.g. see col. 1, especially lines 1-15; col. 7-8) in retroviral vectors (e.g. libraries: see col. 19-20) which are expressed in cells to form libraries (e.g. cells; for screening). The genetic constructs further comprise internal ribosome entry sites (IRES: see col. 17, lines 15-30; col. 27, especially lines 5-20) and "fusion partners" (e.g. see col.

7-12 et seq.) within the scope of the presently claimed invention. Additionally, the reference GFP gene is within the scope of the presently claimed invention (e.g. "a p- or rGFP gene") since it encodes a GFP protein and it meets the presently claimed structural requirement (e.g its a gene); since the presently claimed invention is not limited to any specific genetic sequence.

To the extent that the Anderson et al. reference differs by failing to explicitly teach a renilla(r)GFP gene corresponding to seq. ID 1 (e.g. the elected species) the Bryan et al. Patent reference is cited.

Bryan et al. disclose and claim the use (e.g. diagnostics and "high throughput screening" e.g. libraries) of nucleic acid molecules encoding green fluorescent proteins (e.g. bioluminscent) from the genus Renilla, including Seq. ID No. 15 which is 98.4% (bith best local similarity of 99.4%) homologous to elected seq. ID 1, differing by only one nucleotide (C vs. G). See e.g. Reference Seq. Id 15 and attached Result 4 DATABASE Alignment search. Bryan et al. teach the use of the bioluminescent green fluorescent proteins in cellular assays (e.g. live cells) and in high throughput screening systems (e.g. employing libraries) (e.g. see col. 2-3). Although teaching green fluorescent proteins from other sources, the use of renilla green fluorescent proteins is "more ideal for use as an analytical tool" (e.g. see col. 4-5). According, one of ordinary skill in the art would be motivated to utilize the Bryan et al. renilla green fluorescent proteins, including seq. Id 15, in the Anderson et al. genetic constructs employing green fluorescent proteins since the use of the Bryan et al. renilla green fluorescent proteins is "ideal" for use in the Anderson et al. assays..

Thus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to utilize the Bryan et al. Renilla green fluorescent proteins (including seq. Id 15) in the Anderson et al. genetic constructs for purposes of performing screening assays (e.g. high throughput library screens) in order to obtain the benefits of the renilla protein in such assays as taught by the Bryan reference.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)
January 22, 2003